FOR ARGUMENT

(6)

No. 90-6282

In the Supreme Court of the United States

OCTOBER TERM, 1990

DANIEL TOUBY AND LYRISSA TOUBY, PETITIONERS

v.

UNITED STATES OF AMERICA

ON WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES

KENNETH W. STARR
Solicitor General

ROBERT S. MUELLER, III
Assistant Attorney General

WILLIAM C. BRYSON
Deputy Solicitor General

JEFFREY P. MINEAR
Assistant to the Solicitor General

RICHARD A. FRIEDMAN
Attorney
Department of Justice
Washington, D.C. 20530
(202) 514-2217

---

67 pp

QUESTIONS PRESENTED

1. Whether Section 201(h) of the Controlled Substances Act unconstitutionally delegates to the Attorney General the authority to list a drug temporarily as a schedule I controlled substance.

2. Whether the Attorney General lawfully delegated his authority under Section 201(h) to the Administrator of the Drug Enforcement Administration.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases—Continued: Page

Cases—Continued: Page

Statutes and regulations—Continued: Page

Statutes and regulations—Continued: Page

Miscellaneous:

In the Supreme Court of the United States

OCTOBER TERM, 1990

No. 90-6282

DANIEL TOUBY AND LYRISSA TOUBY, PETITIONERS

v.

UNITED STATES OF AMERICA

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES

OPINIONS BELOW

The opinion of the court of appeals (J.A. 27-66) is reported at 909 F.2d 759. The opinion of the district court (J.A. 2-26) is reported at 710 F. Supp. 551.

JURISDICTION

The judgment of the court of appeals was entered on July 27, 1990. A petition for rehearing was denied on August 21, 1990. The petition for a writ of certiorari was filed on November 19, 1990, and was granted on January 14, 1991. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTE AND REGULATION INVOLVED

Section 201(h) of the Controlled Substances Act, 21 U.S.C. 811(h), and 28 C.F.R. 0.100(b) are set out in Appendix A to this brief.

STATEMENT

Section 201(h) of the Controlled Substances Act, 21 U.S.C. 811(h), provides the Attorney General with a streamlined procedure for temporarily listing a drug as a schedule I controlled substance when he finds that the action is "necessary to avoid an imminent hazard to the public safety." On October 15, 1987, the Attorney General's delegate, the Administartor of the Drug Enforcement Administration (DEA), used that authority to list 4-methylaminorex—a stimulant known in street vernacular as "Euphoria"—temporarily as a schedule I controlled substance pending proceedings for permanent listing. While the temporary listing was in effect, petitioners Daniel and Lyrissa Touby were arrested and charged under the Controlled Substances Act with conspiring to manufacture and knowingly manufacturing 4-methylaminorex. Petitioners do not contend that Euphoria cannot be listed as a schedule I controlled substance, and since their arrest the drug has been permanently listed as such. They challenge their convictions solely on the theory that the Controlled Substances Act's temporary listing provisions unconstitutionally delegate legislative power to the Executive Branch and, alternatively, that the Attorney General unlawfully delegated his authority under the statute to the Administrator of the DEA.

A. The Controlled Substances Act

1. In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act, Pub. L. No. 91-513, 84 Stat. 1236. Title II of that enactment, known as the Controlled Substances Act (CSA), regulates the importation, manufacture, distribution, possession, and improper use of substances that have a detrimental effect on public health and welfare. See CSA § 101, 21 U.S.C. 801. It establishes five schedules of controlled substances, includes a list of substances initially placed on each schedule, and contemplates the periodic reevaluation of the initial lists and the addition of other substances to the schedules. See

CSA § 202, 21 U.S.C. 812. Once a substance is placed on one of the schedules, manufacturers, distributors, and dispensers of the substance must comply with various regulatory requirements. See CSA §§ 301-310, 21 U.S.C. 821-830. Unauthorized possession of the substance with intent to distribute it is a criminal offense. CSA § 401(a), 21 U.S.C. 841(a).[1]

Section 201(a) of the Act, 21 U.S.C. 811(a), grants the Attorney General authority to add substances to the schedules of controlled substances through a rulemaking on the record pursuant to provisions of the Administrative Procedure Act, 5 U.S.C. 553(c), 556, 557. Section 201(b) requires the Attorney General to receive the recommendation of the Secretary of Health and Human Services (HHS) before initiating such a rulemaking respecting a substance proposed for scheduling as a controlled substance. 21 U.S.C. 811(b). The Secretary's recommendations are controlling as to scientific and medical matters, and a substance cannot be placed on the schedules if the Secretary recommends against listing it. Section 201(c) identifies eight factors that the Attorney General and the Secretary of HHS must consider in making their determinations whether a substance should be listed on a controlled substance schedule. 21 U.S.C. 811(c).[2]

---

[1] Petitioners focus exclusively on how the five schedules affect the gradation of criminal penalties applicable to illegal possession or distribution of controlled substances. Pet. Br. 3. Certain of the regulatory requirements of Sections 301-310 also apply differently to the five schedules.

[2] Section 201(c) requires consideration of the following factors relating to the substance under consideration:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

Section 202(b) of the Act identifies the specific criteria for adding a substance to each of the schedules. With exceptions not pertinent here, that provision states that "a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance." 21 U.S.C. 812(b). The findings required to add a substance to schedule I are as follows:

> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
>
> (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

CSA § 202(b)(1), 21 U.S.C. 812(b)(1). Thus, to add a substance to schedule I, the Attorney General must determine through a rulemaking that the substance meets those three criteria in light of the eight factors identified in Section 201(c), 21 U.S.C. 811(c). The scheduling of a substance under Sections 201(a) and 202(b) is subject to judicial review in a court of appeals upon petition by any "aggrieved" person. See CSA § 507, 21 U.S.C. 877.[3]

---

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

21 U.S.C. 811(c).

[3] Aggrieved persons would include manufacturers, distributors, and dispensers subject to the regulatory restrictions of Sections 301 through 310. That class includes petitioners and others who propose to engage in those activities without complying with the regulatory restrictions.

2. In 1984, Congress enacted the Comprehensive Crime Control Act, which amended the Controlled Substances Act in various respects. See Controlled Substances Penalties Amendments Act of 1984, Pub. L. No. 98-473, Tit. II, ch. V, 98 Stat. 2068. Among the amendments, Congress added a new subsection, Section 201(h), to the Controlled Substances Act. That new subsection, codified at 21 U.S.C. 811(h), establishes an expedited procedure for temporarily listing a schedule I substance when the Attorney General finds that such expedition "is necessary to avoid an imminent hazard to the public safety." Section 201(h) "is designed to allow the Attorney General to respond quickly to protect the public from drugs of abuse that appear in the illicit traffic too rapidly to be effectively handled under the lengthy routine control procedures." S. Rep. No. 225, 98th Cong., 1st Sess. 264-265 (1983).

Section 201(h)(3) directs the Attorney General to make the "imminent hazard" determination based on three factors: (1) the drug's history and current pattern of abuse; (2) the scope, duration, and significance of abuse; and (3) the risk to the public health, giving specific consideration to "actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution." 21 U.S.C. 811(h)(3) (incorporating 21 U.S.C. 811(c)(4), (5) and (6)). Section 201(h), however, does not dispense with the requirement that a drug listed on schedule I have the characteristics of a schedule I controlled substance. Hence, to list a substance temporarily on schedule I, the Attorney General must not only make the Section 201(h) "imminent hazard" determination that justifies expedited rulemaking; in accordance with Section 202(b)(1), the substance must also exhibit a high potential for abuse, it must have no currently accepted medical use, and there must be a lack of accepted safety for its use under medical supervision. 21 U.S.C. 812(b)(1).[4]

---

[4] Accordingly, we disagree with petitioners' statements (Br. 5-6, 14 n.9) that Section 202(h) requires only an "imminent hazard"

Before issuing an order listing a substance of a temporary basis under Section 201(h), the Attorney General must publish a notice of proposed listing in the Federal Register and transmit a notice of the proposed order to the Secretary of HHS. CSA § 201(h)(1)(A) and (B), (h)(4), 21 U.S.C. 811(h)(1)(A) and (B), (h)(4). The Attorney General must then wait 30 days after the Federal Register notice and the HHS transmittal before issuing the order. In deciding whether to list a substance following this 30-day period, the Attorney General must take into account any comments submitted by the Secretary of HHS, but the prior approval of the Secretary is not required, as would be the case for a permanent listing. CSA § 201(h)(4), 21 U.S.C. 811(h)(4); compare CSA § 201(b), 21 U.S.C. 811(b).

A Section 201(h) temporary listing expires at the end of one year except that, if the Attorney General has instituted rulemaking proceedings for the permanent listing of the substance under Section 201(a), the Attorney General may extend the temporary listing for up to six months. CSA § 201(h)(2), 21 U.S.C. 811(h)(2). In any event, the temporary listing expires upon the completion of permanent rulemaking respecting the listing of the substance. CSA § 201(h)(5), 21 U.S.C. 811(h)(5). Subsection 201(h)(6) provides that the Attorney General's order temporarily listing a drug as a schedule I substance "is not subject to judicial review." 21 U.S.C. 811(h)(6). This provision postpones the special statu-

---

determination to list a substance in schedule I through expedited rulemaking. As the court of appeals stated, Section 202(b)(1)'s three schedule I criteria are "independent of the factors which section [201(h)] requires the Attorney General to consider in exercising the designated temporary scheduling power." J.A. 38. The Attorney General's determination that the drug poses an "imminent hazard," however, will generally satisfy the first criterion, while his determination that there is no FDA exemption or approval in effect for the drug, see 21 U.S.C. 811(h)(1), will satisfy the second and third criteria. See *Grinspoon* v. *DEA*, 828 F.2d 881, 889 (1st Cir. 1987).

tory review mechanism set forth in Section 507—which, as we have explained, provides "aggrieved parties" with judicial review in the appropriate court of appeals—until the conclusion of permanent rulemaking procedures. See CSA § 507, 21 U.S.C. 877.[5]

3. Congress has provided, through Section 4(c) of the Act of Sept. 6, 1966, ch. 31, 80 Stat. 612, that the Attorney General "may from time to time make such provisions as he considers appropriate authorizing the performance by any other officer, employee, or agency of the Department of Justice of any function of the Attorney General." 28 U.S.C. 510. In addition, Section 501(a) of the Controlled Substances Act provides that the "Attorney General may delegate any of his functions under [the control and enforcement subchapter of the Act] to any officer or employee of the Department of Justice." 21 U.S.C. 871(a).

In 1973, the Attorney General delegated the performance of his duties under the Controlled Substances Act, including the scheduling of drugs, to the Administrator of the DEA. 38 Fed. Reg. 18,380. See 28 C.F.R. 0.100(b) (1986). That delegation was amended in 1987 to clarify that it included the authority to schedule substances on a temporary basis under the expedited procedures of Section 201(h). 52 Fed. Reg. 24,447. See 28 C.F.R. 0.100(b).[6]

---

[5] For the reasons discussed below, at pp. 33-36, Section 201(h)(6) does not preclude a court from determining whether a designated drug is properly listed as a schedule I substance in the course of a criminal enforcement proceeding. Accordingly, we disagree with petitioners' contrary characterizations of the statute. See Pet. Br. 5, 26-28.

[6] The Attorney General's 1987 subdelegation was issued in response to a court of appeals decision holding that the 1973 subdelegation to the Administrator did not encompass the later-enacted authority conferred by Section 201(h). See *United States* v. *Spain*, 825 F.2d 1426 (10th Cir. 1987).

B. The Temporary Listing Of Euphoria As A Schedule I Controlled Substance

1. On August, 13, 1987, the Administrator of the DEA proposed the temporary listing of 4-methylaminorex (formally known as (±) *cis*-4, 5-dihydro-2-amino-4-methyl-5-phenyl-2-oxazolamine) as a schedule I controlled substance. 52 Fed. Reg. 30,174.[7] The Administrator observed that the drug "is a new substance that is clandestinely produced, that is distributed in illicit traffic, and that produces stimulant effects," and therefore "is certainly the type of drug which Congress intended to be considered for emergency scheduling." *Ibid.* Citing various studies, the Administrator also noted that 4-methylaminorex's pharmacological profile resembles that of amphetamine; that in high doses it produces "seizure activity in the brain and associated convulsions, depression, respiratory failure, and death"; and that the DEA was not aware of any commercial manufacturers or suppliers of the drug or of any approved therapeutic use. *Id.* at 30,175.

The Administrator made the necessary findings for listing under Sections 201(h) of the Controlled Substances Act. He considered the history, pattern, and significance of abuse, and the risk the drug posed to public safety. 52 Fed. Reg. 30,174. See CSA § 201(h)(3), 21 U.S.C. 811(h)(3). He also identified the characteristics necessary to qualify the substance for schedule I listing, referring to "the potent stimulant and toxic actions of the substance, and the lack of accepted medical use or established safety for the use of 4-methylaminorex." 52 Fed. Reg. at 30,174. See CSA § 202(b)(1), 21 U.S.C.

[7] The (±) prefix indicates that the listed substance is actually a mixture of two optical isomers. Under the Controlled Substances Act's definitions, the listing of 4-methylaminorex includes the substance's individual optical isomers. See CSA § 102(14), 21 U.S.C. 802(14); 21 C.F.R. 1308.02(c) and 1308.11(f). In addition to its street name and formal chemical name, 4-methylaminorex is also identified in pharmacology studies as "U4Euh," "ICE," and "McN-822."

812(b)(1). Based on a consideration of the factors required by Section 201(h)(3), as well as the finding that the drug qualified as a schedule I controlled substance under Section 202(b)(1), the Administrator concluded that listing 4-methylaminorex in schedule I, at least on a temporary basis, was "necessary to avoid an imminent hazard to the public safety." 52 Fed. Reg. 30,175. Pursuant to Section 201(h)(4), the Administrator notified the Assistance Secretary of Health and Human Services of the proposed scheduling. *Ibid.*

2. On October 15, 1987, the Administrator published an order temporarily listing 4-methylaminorex as a schedule I controlled substance, effective on that date. 52 Fed. Reg. 38,225. In response to the notice of intent to schedule the drug, the Food and Drug Administration (FDA) of HHS had advised the DEA that it had no objections to the schedule I listing of the substance. *Ibid.* No comments were received from any other interested parties. *Ibid.* Based on the information discussed in the August 13 notice of proposed listing, the Administrator stated his finding that the temporary listing of the drug as a schedule I controlled substance was necessary to avoid an imminent hazard to the public safety. *Id.* at 38,225-38,226. The notice specifically warned that any unauthorized activity respecting the drug was henceforth unlawful and subject to criminal penalties. *Ibid.*

3. On October 13, 1988, the Administrator extended the duration of the temporary listing for an additional six months, through April 15, 1989, or until completion of rulemaking proceedings to schedule the drug on a permanent basis, whichever occurred first. 53 Fed. Reg. 40,061. The next day, he issued a notice of intent to schedule the drug permanently. 53 Fed. Reg. 40,391.[8] On April 13, 1989, 4-methylaminorex was permanently

[8] That decision was based, in part, on a recommendation by the DEA's Drug Control Section. See 53 Fed. Reg. 40,391. We have reprinted that recommendation, which is part of the administrative record, as an appendix to this brief. See App. B, *infra*.

listed as a schedule I controlled substance after the completion of rulemaking under Section 201(a). 54 Fed. Reg. 14,799.

C. The Facts And Proceedings In This Case

1. On January 5, 1989, police officers in Wanaque, New Jersey, arrested petitioners after they purchased a television set with a counterfeit cashier's check. A search incident to the arrest found petitioners to be in possession of marijuana and drug paraphernalia. Based on further investigation, a warrant was obtained to search petitioner's home for counterfeiting materials and drugs. When DEA agents executed the warrant on January 6, 1989, they discovered a fully operational drug laboratory in petitioners' bedroom. Among the items seized were papers containing the formula for manufacturing 4-methylaminorex. Also seized were mixtures that, upon testing, were found to contain the drug.[9] J.A. 19-21 49-50.

2. On January 11, 1989, a grand jury in the United States District Court for the District of New Jersey returned a two-count indictment charging petitioners with unlawful manufacture of a schedule I controlled substance and conspiracy to manufacture that substance, in violation of the Controlled Substances Act. See CSA §§ 401(a), 406, 21 U.S.C. 841(a), 846. At the time of the alleged offenses, the Administrator of the DEA had temporarily listed 4-methylaminorex as a schedule I controlled substance pursuant to Section 201(h), but he had not completed the rulemaking for permanent listing of the substance. J.A. 2, 28.

---

[9] In September 1988, Daniel Touby had purchased cyanogen bromide from the Eastman Kodak Company. In October 1988, Lyrissa Touby had obtained sodium acetate, sodium carbonate, potassium carbonate, and norephedrine hydrochloride from a chemical supplier. Expert testimony established that those chemicals are used to make 4-methylaminorex. J.A. 49.

Petitioners challenged the constitutionality of Section 201(h) in a pretrial motion to dismiss the indictment. They contended that Congress had impermissibly delegated to the Attorney General legislative power to criminalize activity concerning 4-methylaminorex by authorizing him to list the drug as a schedule I controlled substance on a temporary basis. Petitioners also contended that the Attorney General could not in any event delegate his temporary listing authority to the Administrator. The district court rejected both challenges in an opinion dated March 17, 1989. J.A. 11-19. After a jury trial, petitioners were convicted as charged in the indictment. Daniel Touby was sentenced to 42 months' imprisonment and Lyrissa Touby was sentenced to 27 months' imprisonment, each term of imprisonment to be followed by three years' supervised release. J.A. 28.

3. The court of appeals affirmed petitioners' convictions, rejecting their challenges to the temporary scheduling procedure. J.A. 27-54. The court first held that Congress had not impermissibly delegated its legislative power to the Attorney General by authorizing him to list drugs as controlled substances on a temporary basis.[10] J.A. 33-43. It noted that this Court has sustained broad assignments of authority to the Executive Branch, as long as the relevant congressional enactment lays down an "intelligible principle" directing the responsible official's actions. *Id.* at 34-35, quoting *Mistretta* v. *United States*, 488 U.S. 361, 372 (1989), and *J.W. Hampton, Jr., & Co.* v. *United States*, 276 U.S. 394, 409 (1928).

The court rejected petitioners' contention that a more stringent nondelegation standard should be applied in

---

[10] The Ninth Circuit reached the same result in *United States* v. *Emerson*, 846 F.2d 541, 545-546 (1988). The Tenth Circuit has held, however, that Section 201(h) is an unconstitutional delegation of legislative power. *United States* v. *Widdowson*, 916 F.2d 587, 589-591 (1990).

this case because Section 201(h) permits the Attorney General to "create" crimes. J.A. 35-38. It explained that this Court has not in fact applied a more stringent test in considering the validity of statutes authorizing administrative regulation of conduct giving rise to criminal liability, J.A. 36-37, and that Section 201(h) does not authorize the Attorney General to define primary criminal conduct, because Congress itself has proscribed the manufacture and possession of controlled substances, while the Attorney General "merely designat[es] the drugs or substances which fall within Congress' general description." J.A. 37-38.

Applying this Court's "intelligible principle" test, the court of appeals concluded that Section 201(h) provides the Attorney General with sufficient guidance for making the "imminent hazard" finding required for temporary listing of substances. J.A. 39-40. The court observed that the statutory standards provide at least as much guidance as the "public interest, convenience, interest, or necessity" standard that was found to be sufficient to guide the Federal Communications Commission in *National Broadcasting Co.* v. *United States*, 319 U.S. 190, 225-227 (1943), or the "excessive profits" standard for renegotiation of wartime contracts that was sustained in *Lichter* v. *United States*, 334 U.S. 742, 783-787 (1948). J.A. 39-40.

Moreover, the court of appeals found that the constitutionality of Section 201(h) was reinforced by the limited scope of the temporary scheduling, which "can be viewed as preliminary to and in aid of the permanent scheduling authority as set forth in section [201(a)]," J.A. 40, and by the practical necessities of the situation confronting Congress. The court observed that Congress had found the permanent listing procedures inadequate to address the situation of "designer drugs" that are similar to listed substances but contain slight variations, and it noted that the purpose of the temporary listing authority is to "avoid an imminent hazard to the public

safety," 21 U.S.C. 811(h)(1), by imposing an "'emergency control'" during the interim between identification of a drug that presents a major abuse problem and the permanent scheduling of the substance—a period during which "'enforcement actions against traffickers [were] severely limited and a serious health problem may arise.'" J.A. 39, 40 (quoting S. Rep. No. 225, *supra*, at 264, 265).

Finally, the court rejected petitioners' contention that Section 201(h)(6)'s limitation on judicial review of an order listing a drug on a temporary basis renders Section 201(h) an unconstitutional delegation of legislative power. J.A. 41-43. The court pointed out that Congress has foreclosed judicial review in a variety of other administrative contexts. J.A. 42-43. It also stated that Section 201(h)(6) does not necessarily bar judicial review of the temporary listing in a criminal prosecution, if the defendant claims that the listing of the particular drug violated the standards in Section 201(h). J.A. 33 n.2, 42-43. But in this case, the court noted, petitioners "do not contend that Euphoria cannot be scheduled as a Schedule I narcotic or that the temporary scheduling of the substance did not meet the standards set forth in 21 U.S.C. § 811(h)." J.A. 33.

The court of appeals next held that Section 4(c) of the Act of September 6, 1966, 28 U.S.C. 510, empowered the Attorney General to delegate his temporary listing authority to the Administrator of the DEA.[11] J.A. 43-46. The court cited the general rule that in the absence of a contrary expression by Congress, powers conferred on an Executive Branch officer may be delegated to a subordinate official, J.A. 45, and it found no support for the proposition that Congress intended *sub silentio* to create an exception to the Attorney General's broad delegation authority under Section 4(c) in the context

[11] The Tenth Circuit has reached the opposite conclusion, holding that the Section 201(h) authority is nondelegable. *United States* v. *Widdowson*, 916 F.2d at 591-593.

of the listing of controlled substances on a temporary basis pursuant to Section 201(h).[12] The court further found that the Attorney General did, in fact, delegate his Section 201(h) authority to the Administrator. J.A. 46-48.

Judge Hutchinson dissented. J.A. 54-66. He agreed with the majority that the record did not suggest that the Attorney General acted arbitrarily or otherwise improperly in temporarily listing Euphoria as a controlled substance under Section 201(h) or that Euphoria is not a danger to the public safety. J.A. 55. Judge Hutchinson also accepted the majority's analysis of the statutory background and the nature of the problem to which Section 201(h) is addressed, J.A. 55, and he concluded that Section 201(h)'s purpose of avoiding "'an imminent hazard to the public safety' is in and of itself an intelligible principle under the teachings of the Supreme Court." J.A. 58, citing *National Broadcasting Co.* v. *United States*, 319 U.S. at 225-226, and *Lichter* v. *United States*, 334 U.S. at 783-787. But Judge Hutchinson nevertheless believed that Section 201(h) unconstitutionally delegates Congress's legislative power because, in his view, it authorizes the Attorney General to define primary criminal conduct and therefore should be subject to a more stringent non-delegation test. J.A. 58-61.[13]

---

[12] Because the court found adequate subdelegation authority under Section 4(c), it did not reach the question whether Section 501(a) of the Controlled Substances Act, 21 U.S.C. 871(a), provided an independent basis for such delegation. J.A. 46 n.4.

[13] Because he believed that Section 201(h) is unconstitutional, Judge Hutchinson did not reach the question of the statutory validity of the Attorney General's delegation of his temporary listing authority to the Administrator of the DEA. J.A. 55 n.1.

SUMMARY OF ARGUMENT

1. The Constitution divides and diffuses governmental power among the "three coequal Branches." *Mistretta* v. *United States*, 488 U.S. 361, 380 (1989). This Court's requirement that Congress provide an intelligible principle to guide an executive officer's administration of a statute maintains that separation of powers by assuring that no "legislative power"—as the Constitution uses that term—is delegated to the Executive Branch. Once it is determined, through application of that standard, that Congress has conferred only executive functions, the delegation inquiry is at an end. Separation of powers principles do not prevent Congress from selecting the Attorney General, rather than another Executive Branch official, to perform the executive function. Indeed, Congress had sound policy reasons for vesting the Attorney General with the Section 201(h) temporary listing authority, and the potential for abuse that petitioners posit simply does not exist.

Petitioners are also mistaken in arguing that Section 201(h) is an unconstitutional delegation because Congress has provided inadequate opportunity for judicial oversight of the Attorney General's temporary listing decisions. A temporary listing of a substance is simply the first step in the administrative process for determining whether the substance should be permanently listed. As petitioners recognize, Section 507 of the Controlled Substances Act specifically authorizes judicial review if the substance is permanently listed. 21 U.S.C. 877. Petitioners object, however, that Section 201(h)(6) precludes Section 507 review during the interim period of up to 18 months while the permanent rule is under consideration and the temporary listing is in effect. There is no merit to that objection. Individuals who insist on manufacturing and selling hazardous substances during that interim period may challenge the Attorney General's listing decision in a criminal enforcement pro-

ceeding. The government is not required to stay its hand until the courts have an opportunity to determine whether government is justified in bringing an enforcement action. See *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 598-599 (1950).

2. Petitioners also argue that the Attorney General lacks statutory authority to delegate his Section 201(h) responsibilities to the Administrator of the DEA. Congress, however, has authorized that subdelegation under two separate statutes. First, Congress has given the Attorney General broad authority to delegate the performance of "any" of his functions to another officer, employee, or agency of the Department of Justice. 28 U.S.C. 510. Second, Congress specifically provided in Section 501(a) of the Controlled Substances Act that the Attorney General "may delegate any of his functions" under the control and enforcement provisions of that Act to any officer or employee of the Department. 21 U.S.C. 871(a). There is no indication in the Controlled Substances Act that Congress intended to except the Attorney General's responsibilities under Section 201(h) from those delegation provisions. The Attorney General accordingly had ample statutory authority to delegate his Section 201(h) responsibilities to the Administrator of the DEA.

ARGUMENT

I. SECTION 201(h) DOES NOT VIOLATE THE CONSTITUTION'S REQUIREMENT THAT "ALL LEGISLATIVE POWERS" SHALL BE VESTED IN CONGRESS

The Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const. Art. I, § 1. Petitioners contend that Congress has violated that requirement by creating schedules of controlled substances, providing the initial contents of those schedules, and then authorizing the Attorney General to add—temporarily, pending formal rulemaking—other substances that he has identified as posing "an imminent hazard to the public safety." § 201(h), 21 U.S.C. 811(h). Although petitioners contend that Congress's action is "unprecedented" (Br. 15), "strikes at the heart of the system of checks and balances that guarantee the rule of law" (Br. 15) and undermines individual liberty "at its core" (Br. 18), they also recognize that this Court's precedents narrowly restrict the scope of their challenge.

Petitioners accept that "the separation-of-powers principle, and the nondelegation doctrine in particular, do not prevent Congress from obtaining the assistance of its coordinate Branches." *Mistretta* v. *United States*, 488 U.S. 361, 372 (1989). They also accept (Br. 12-13, 21) the principle "now enshrined in our jurisprudence" that:

> "In determining what [Congress] may do in seeking assistance from another branch, the extent and character of that assistance must be fixed according to common sense and the inherent necessities of the government coordination."

Mistretta, 488 U.S. at 372, quoting *J.W. Hampton, Jr., & Co.* v. *United States*, 276 U.S. 394, 406 (1928).

Petitioners acknowledge that "Congress has often granted executive departments and agencies the authority to promulgate regulations that govern private con-

duct, and some of the resulting regulations are enforceable through criminal prosecutions." Br. 19. See, *e.g.*, *Yakus* v. *United States*, 321 U.S. 414 (1944); *United States* v. *Grimaud*, 220 U.S. 506 (1911). And they acknowledge, more indirectly (Br. 13 & n.7, 22 n.14, 24), the firmly established rule that

> [s]o long as Congress "shall lay down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform, such legislative action is not a forbidden delegation of legislative power."

Mistretta, 488 U.S. at 372, quoting *J.W. Hampton, Jr., & Co.*, 276 U.S. at 409.[14]

Petitioners do not claim that Congress has failed to set forth an "intelligible principle" to guide the Attorney General's listing of substances on a temporary or permanent basis. Indeed, they expressly disclaim any challenge to "the specificity of the substantive standards that Congress established to govern the exercise of delegated powers." Br. 13, 21. And, as the court of appeals stated,

---

[14] Petitioners also acknowledge (Br. 22 n.14), as recited in *Mistretta*, that this Court's application of the "intelligible principle" test has resulted in rejection of virtually every challenge to legislation on the ground that it unconstitutionally delegated legislative power. 488 U.S. at 373-374. See, *e.g.*, *Lichter* v. *United States*, 334 U.S. 742 (1948) (authority to determine excess profits); *American Power & Light Co.* v. *SEC*, 329 U.S. 90 (1946) (authority to prevent unfair or inequitable distribution of voting power among security holders); *Yakus* v. *United States*, 321 U.S. 414 (1944) (authority to fix commodity prices at fair and equitable levels); *FPC* v. *Hope Natural Gas Co.*, 320 U.S. 591 (1944) (authority to determine just and reasonable rates) *National Broadcasting Co.* v. *United States*, 319 U.S. 190 (1943) (authority to regulate broadcast licensing as public interest, convenience, or necessity require). The only two exceptions, *Panama Refining Co.* v. *Ryan*, 293 U.S. 388 (1935), and *A.L.A. Schechter Poultry Corp.* v. *United States*, 295 U.S. 495 (1935), involved a statute in which Congress "failed to articulate any policy or standard that would serve to confine the discretion of the authorities to whom Congress had delegated power." *Mistretta*, 488 U.S. at 373 n.7.

petitioners "do not contend that Euphoria cannot be scheduled as a Schedule I narcotic or that the temporary scheduling of the substance did not meet the standards set forth in 21 U.S.C. § 811(h)." J.A. 33.

Ultimately, petitioners seek an exception to this Court's settled delegation principles based on two points: the Attorney General (rather than some other executive official) exercises the authority conferred under the statute (Br. 14-23); and the statute's temporary listing provisions do not provide for pre-enforcement review (Br. 24-35). As we explain below, Congress's conferral of authority in this case is plainly constitutional under this Court's settled standards and is not, as petitioners suggest, "unprecedented" (Br. 15, 19, 30). The factors that petitioners claim distinguish this case—the identity of the particular executive officer who exercises the delegated authority, and the timing of judicial review—do not call for a different analysis or dictate a different result.

A. Section 201(h) Satisfies Established Delegation Standards

Petitioners face a difficult task in demonstrating that a duly enacted congressional statute is facially unconstitutional. See, *e.g.*, *Mistretta*, 488 U.S. at 384; *United States* v. *Salerno*, 481 U.S. 739, 745 (1987); *Rostker* v. *Goldberg*, 453 U.S. 57, 64 (1981). That task is especially difficult in this case because, as the lower courts held and petitioners concede, Congress's delegation of authority to the Attorney General under Section 201(h) amply satisfies the "intelligible principle" test that this Court has consistently employed to determine the constitutionality of challenged delegations. See *Skinner* v. *Mid-America Pipeline Co.*, 490 U.S. 212, 218-219, 224 (1989); *Mistretta*, 488 U.S. at 372-374.

1. Sections 201(h) and 202(b) set forth "intelligible" —and indeed quite precise—standards to channel the Attorney General's discretion in identifying substances for temporary listing as schedule I controlled substances. First, the substance must present "an imminent hazard

to the public safety," CSA § 201(h)(1), 21 U.S.C. 811(h)(1), as determined after consideration of the substance's history and current pattern of abuse, the scope, duration and significance of abuse, the risk to the public health, the diversion from legitimate channels, and clandestine importation, manufacture, or distribution, CSA § 201(c)(4)-(6), (h)(3), 21 U.S.C. 811(c)(4)-(6), 811(h)(3). Second, to qualify for listing on schedule I, a substance must have "a high potential for abuse," it must have "no currently accepted medical use in treatment in the United States," and there must be "a lack of accepted safety for use of the drug or other substance under medical supervision." CSA § 202(b)(1), 21 U.S.C. 812(b)(1).[15] There is no question in this case that these standards meet the "intelligible principle" test for upholding Congress's delegation of authority.

2. While petitioners state that they do "not challenge the specificity of the substantive standards that Congress established to govern the exercise of [the Section 201(h)] delegated powers," Pet. Br. 13, 21, they nevertheless claim that the Attorney General may act with "unfet-

[15] A proposed, but not enacted, version of Section 201(h) would have authorized the Attorney General to list a substance on any schedule for which it qualified, but would have given the Secretary of HHS authority to veto the expedited scheduling. See S. 1762, 98th Cong., 1st Sess. (1983), as reported in S. Rep. No. 225, *supra*, at 616-617. The enacted version, however, authorized the Attorney General to list temporarily only schedule I substances and eliminated the Secretary's veto power. The House Committee on the Judiciary explained:

> In examining the particular substances for which the scheduling action was most necessary, the Subcommittee concluded that limiting the authority only to substances that have no currently accepted medical use in treatment addressed both the legitimate concerns of those in the health care industry and the principal danger to the public health.

H.R. Rep. No. 835, 98th Cong., 2d Sess. 10 (1984). In short, the health care industry's concerns were accommodated, and the need for the Secretary's veto power were eliminated, by limiting the temporary scheduling authority to schedule I substances. See note 4, *supra*.

tered discretion" in selecting "any drug" for emergency schedule I listing under Section 201(h), Pet. Br. 14, 24. Petitioners overlook the significance of the requirements that a substance listed on an emergency basis must both pose an "imminent hazard" and meet the three criteria for schedule I listing set in out Section 202(b)(1). See Pet. Br. 14 n.9. For example, one of the key distinctions drawn by Section 202(b) between schedule I substances and substances qualifying for inclusion on the other schedules is the lack of a "currently accepted medical use in treatment in the United States." 21 U.S.C. 812(b)(1)(B). Each of the other schedules includes substances that have a currently accepted medical use. See 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B), and (5)(B). Thus, petitioners' suggestion (Br. 24) that the Attorney General "could add a substance as innocuous as aspirin to Schedule I" is not only farfetched, but is precluded by the statute.[16]

3. Petitioners also suggest (Br. 15-16, 30-31) that when Congress delegates authority to the Executive Branch to identify specific conduct that may result in criminal prosecution there is a need for "heightened constitutional concerns." This Court, however, has never rejected application of the "intelligible principle" test in the criminal context. The relevant inquiry remains whether Congress has set forth standards sufficiently

[16] Other passages of petitioners' brief seem to suggest that Section 201(h) was intended to regulate only fundamentally new drugs. See Br. 6 n.3, 14 n.9. Congress recognized, however, that a drug (such as naturally occurring peyote) may exist long before there emerges a need—resulting from the drug's abuse—to control its distribution. Hence, there is no requirement that the drug be "newly designed or created" (Pet. Br. 6 n.3). Instead, to qualify for temporary listing under Section 201(h), the substance must not already be listed on any of the schedules, the substance must not be subject to an exemption or approval under the FDA's new-drug provisions of 21 U.S.C. 355, and the temporary listing of the substance must be "necessary to avoid an imminent hazard to the public safety." CSA § 201(h)(1), 21 U.S.C. 811(h)(1).

specific to guide the executive official's exercise of discretion. Cf. *Skinner*, 490 U.S. at 222-223 (rejecting the "application of a different and stricter nondelegation doctrine in cases where Congress delegates discretionary authority to the Executive under its taxing power").[17]

For example, in *Yakus* v. *United States*, 321 U.S. 414 (1944), this Court upheld a delegation of authority to fix maximum commodity prices and rents even though violation of the regulations was a criminal offense. There was no suggestion in that case that a more stringent standard of delegation applied. Similarly, in *J.W. Hampton, Jr., & Co.*, 276 U.S. at 406, the Court observed that Congress frequently secures the "the exact effect" of legislation by vesting discretion in executive officers to make regulations "directing the details of its execution, even to the extent of providing for penalizing a breach of such regulations." 276 U.S. at 406. Indeed, the instances are legion where Congress has authorized Executive Branch agencies to prescribe regulations or to make administrative determinations that may result in the imposition of criminal punishment.[18] This Court has repeatedly upheld such au-

[17] Petitioners rely on statements in *Mistretta* and *Fahey* v. *Mallonee*, 332 U.S. 245, 250 (1947), that characterize the statute at issue in *Schechter Poultry* and *Panama Refining* as delegating power to make "federal crimes of acts that never had been such before" and to create "new crimes in uncharted fields." *Fahey*, 332 U.S. at 249, 250; see *Mistretta*, 488 U.S. at 373 n.7. The point of those statements was not that a different constitutional standard applies to regulations with penal consequences, but rather that the delegations at issue in *Schechter Poultry* and *Panama Refining* were unconstitutional because "Congress had failed to articulate *any* policy or standard that would serve to confine the discretion of the authorities to whom Congress had delegated power." *Mistretta*, 488 U.S. at 373 n.7 (emphasis added).

[18] See, *e.g.*, 7 U.S.C. 87b(a)(11), 87c (Department of Agriculture grain regulations); 7 U.S.C. 2024(b) (Department of Agriculture food stamp regulations); 15 U.S.C. 78ff (violation of Securities and Exchange Commission regulations); 15 U.S.C. 2070 (violation of Consumer Product Safety Commission regulations); 15 U.S.C. 2615(b) (violation of Environmental Protection Agency

thorizations without regard to their penal consequences. See, *e.g.*, *Avent* v. *United States*, 266 U.S. 127 (1924); *McKinley* v. *United States*, 249 U.S. 397 (1919); *United States* v. *Grimaud*, 220 U.S. 506 (1911); *Monongahela Bridge Co.* v. *United States*, 216 U.S. 177 (1910); *Union Bridge Co.* v. *United States*, 204 U.S. 364 (1907); *In re Kollock*, 165 U.S. 526 (1897).[19]

4. Congress's prescription of "intelligible principles" is sufficient, by itself, to assure that Section 201(h) does not delegate "legislative power"—in the sense the Constitution uses that term—to the Executive Branch. See *Skinner*, 490 U.S. at 218-219. Indeed, prior to the devel-

toxic substance control regulations); 15 U.S.C. 3414(c)(2) (violation of Federal Energy Regulatory Commission natural gas regulations); 16 U.S.C. 773g (violation of International Pacific Halibut Commission regulations); 19 U.S.C. 1436(c), 1459(g) (violation of Presidential regulations pertaining to international investment); 29 U.S.C. 666(e) (violation of Occupational Safety and Health Administration regulations); 30 U.S.C. 1268 (violation of Department of Interior orders); 31 U.S.C. 5322 (violation of Department of Treasury regulations respecting monetary instruments transactions); 33 U.S.C. 1319, 1415 (violation of EPA water quality regulations); 42 U.S.C. 4910(a) (violation of EPA noise control regulations); 42 U.S.C. 6928(d) (violation of EPA solid waste management regulations); 42 U.S.C. 6992d (violation of EPA medical waste regulations); 42 U.S.C. 8432 (violation of Department of Energy regulations); 42 U.S.C. 9603 (violation of EPA hazardous substance reporting requirements); 43 U.S.C. 1350 (violation of Department of Interior regulations respecting outer continental shelf leasing); 46 U.S.C. 3718(b) (violation of Department of the Treasury regulations respecting inspection of vessels); 49 U.S.C. 521(b)(6), 11903 (violation of Interstate Commerce Commission requirements).

[19] Even if delegations involving the creation of novel criminal liability warranted closer scrutiny, that scrutiny would not be necessary in this case. As the court of appeals observed, the Attorney General has had authority since 1970 to identify substances for permanent placement on schedule I, and the courts have repeatedly upheld that authority. J.A. 37. Congress, not the Attorney General, has prescribed the elements of the criminal offenses involving such substances and has defined the penalties. Thus, the scope of the Attorney General's delegated authority is quite narrow.

opment of that test, this Court repeatedly stated that statutes conditioning the application of the law on executive determinations do not delegate lawmaking authority at all; rather, they confer "an authority or discretion as to its execution, to be exercised under and in pursuance of the law." *J.W. Hampton, Jr., & Co.*, 276 U.S. at 407, and *Field* v. *Clark*, 143 U.S. 649, 693-694 (1892), quoting *Cincinnati, W. & Z. R.R.* v. *Commissioners of Clinton County*, 1 Ohio St. 77, 88-89 (1852).[20]

[20] For example, in *United States* v. *Grimaud, supra*, the Court observed that the Secretary of Agriculture "did not legislate" when he promulgated criminally enforceable grazing regulations pursuant to the laws establishing national forests because he "did not go outside of the circle of that which the act itself had affirmatively required to be done, or treated as unlawful if done." 220 U.S. at 518. Rather, the Secretary was fulfilling the executive function "to administer the law and carry the statute into effect." *Ibid.*

Similarly, in *Monongahela Bridge Co.* v. *United States, supra*, the Court rejected an unlawful delegation claim in a criminal prosecution based on the Secretary of War's administrative determination that a bridge constituted an obstruction to navigation under Section 18 of the Rivers and Harbors Appropriation Act of 1899, ch. 425, 30 Stat. 1151. 216 U.S. at 192. Justice Harlan stated for the Court that the Secretary "could not be said to exercise strictly legislative or judicial power" where he simply determines, pursuant to congressional directive, "some facts or some state of things upon which the enforcement of [a statute] may depend." *Id.* at 193.

The Court reached the same result under similar facts in *Union Bridge Co.* v. *United States*, 204 U.S. at 386 ("In performing that duty the Secretary of War will only execute the clearly expressed will of Congress, and will not, in any true sense, exert legislative or judicial power."). See also, *e.g.*, *Field* v. *Clark*, 143 U.S. at 694 ("The legislature cannot delegate its power to make a law; but it can make a law to delegate a power to determine some fact or state of things upon which the law makes, or intends to make, its own action depend."); *In re Kollock*, 165 U.S. at 533 ("The regulation was in execution of, or supplementary to, but not in conflict with, the law itself, and was specifically authorized thereby in effectuation of the legislation which created the offense."); *Cargo of the Brig Aurora* v. *United States*, 11 U.S. (7 Cranch) 382, 388 (1813) ("we can see no sufficient reason, why the legislature should not exercise its discretion * * * either expressly or conditionally, as their judgment should direct").

The Court's "intelligible principle" standard has further refined that reasoning by recognizing that if Congress has failed to articulate intelligible principles to guide the executive officer's exercise of discretion under the statute, there may be a de facto delegation of legislative power. See *Mistretta*, 488 U.S. at 418-419 (Scalia, J., dissenting). Once it is determined, however, that the executive officer is executing Congress's will pursuant to ascertainable legislative guidelines, that is the end of the delegation inquiry. In cases such as this one, where Congress has set forth specific standards to direct the Attorney General's exercise of discretion, there is no delegation of legislative power at all. See *Mistretta*, 488 U.S. at 379.

B. The Constitution Does Not Prohibit Congress From Authorizing The Attorney General To Exercise The Authority Conferred By Section 201(h)

Petitioners argue that satisfaction of this Court's "intelligible principle" standard is not enough in this case. They contend (Br. 14-23) that Section 201(h) violates delegation principles by committing the temporary scheduling decision to the Attorney General rather than to some other executive official, such as the Secretary of HHS. Petitioners assert (Br. 14) that Congress's choice results in an "unconstitutional aggregation of power" because it gives the Attorney General "unilateral authority to create crimes and prosecute violators." This novel argument misconceives both the nature of the Constitution's separation of powers principle and the specific responsibilities of the Attorney General.

1. This Court "consistently has given voice to, and has reaffirmed, the central judgment of the Framers of the Constitution that, within our political scheme, the separation of governmental powers into three coordinate Branches is essential to the preservation of liberty." *Mistretta*, 488 U.S. at 380. But the concept of separation of powers always focuses on the distribution of powers among the "three coequal Branches." *Ibid.* What is for-

bidden are "provisions of law that either accrete to a single Branch powers more appropriately diffused among separate Branches or that undermine the authority and independence of one or another coordinate Branch." *Id.* at 382.

This Court has never suggested that separation of powers principles govern the aggregation of powers within subdivisions of the Executive Branch. Indeed, the Constitution provides no premise for such an approach because it vests all executive power in the President, U.S. Const. Art. II, § 1, and requires him to see that the laws are "faithfully executed," U.S. Const. Art. II, § 3. From a constitutional perspective, the Executive Branch's authority to administer statutes through the promulgation of regulations is necessarily and always aggregated with the Executive Branch's authority to enforce the law through penal and other legislatively prescribed means. The promulgation of regulations and the prosecution of offenses are simply different aspects of the Executive's function.

2. Petitioners recognize that there is nothing novel in Congress authorizing Executive Branch officials to proscribe dangerous substances upon determination that the substances pose an "imminent hazard to the public safety" and to enforce those proscriptions through criminal penalties. CSA § 201(h), 21 U.S.C. 811(h).[21] They concede that "the need for flexibility and expertise may well justify delegation of the temporary scheduling power to some

[21] Compare, *e.g.*, 15 U.S.C. 2605(d) (authorizing the Administrator of the Environmental Protection Agency to impose immediate restrictions on the manufacture of toxic substances that pose an unreasonable risk of serious or widespread injury); 21 U.S.C. 355(e) (authorizing the Secretary of Health and Human Services to suspend approval of new drugs upon finding an imminent hazard to public health health); 29 U.S.C. 655(c) (authorizing the Secretary of Labor to promulgate emergency temporary occupational safety standards); 30 U.S.C. 811(b) (authorizing the Secretary of Labor to promulgate emergency temporary mine safety standards). See also note 18, *supra*.

executive officer." Br. 22. Petitioners argue (Br. 15, 22-23), however, that Congress should have vested the Secretary of HHS, rather the Attorney General, with the authority to make the temporary listing decision to avoid aggregating "criminal lawmaking and prosecutorial power." That argument, however, does really not rest on the constitutional doctrine of separation of powers, but simply challenges the wisdom of a legislative policy judgment.[22]

Petitioners err at the outset by simply *assuming* that Congress has delegated "criminal lawmaking" power to the Attorney General—even though, as they concede, Congress has provided an "intelligible principle" to control the executive's exercise of discretion. As we have explained (pp. 19-25, *supra*), Congress's articulation of clear standards to guide executive discretion ensures that the Attorney General performs only executive functions. That should end the delegation inquiry. The extent to which a particular function is executive in nature does not depend on which Executive Branch official performs the function. Indeed, petitioners are unable to cite a single instance in which this Court has invalidated any Act of Congress on the ground that it gave one Executive Branch official, rather than another, authority over a particular executive function.

[22] The Constitution does not create a Department of Justice and a separate Department of Health and Human Services. Under the constitutional scheme, Congress could create a Department of Justice, Health, and Human Services, headed by a single official. Or, it could make all of the Executive Branch departments subunits within a single entity headed by one officer of the United States acting under the direction of the President. Nothing in the Constitution would prohibit such a scheme, as long as the President remained supreme over the Executive Branch. Because the functions of different departments could be performed by a single department without violating separation of powers principles, it makes no sense to say that separation of powers principles are offended if the executive functions of scheduling and enforcement are performed within a single department, rather than separate departments within the Executive Branch.

Congress has broad authority, under the Necessary and Proper Clause, U.S. Const. Art. I, § 8, Cl. 18, to create or select the appropriate Executive Brance officer to perform a particular executive function. Congress vested the Attorney General with authority to make temporary scheduling decisions because, in Congress's judgment, the Attorney General is best situated to determine whether a substance poses an "imminent hazard to the public safety." Specifically, Congress enacted the temporary listing provisions to deal with the emergent *abuse* of unlisted drugs. CSA § 201(h)(3), 21 U.S.C. 811(h)(3) (requiring that the imminent hazard determination be based on considerations related to abuse and risk to the public health). As a general matter, the Controlled Substances Act vests the Attorney General with primary responsibility for determining abuse characteristics. See CSA § 201(b), 21 U.S.C. 811(b) (restricting the Secretary of HHS to consideration of the "scientific or medical" aspects of abuse characteristics). Thus, it is quite reasonable that Congress would vest the Attorney General, rather than the Secretary of HHS, with the imminent hazard determination.

Congress's decision that the Attorney General, rather than the Secretary of HHS, should make the imminent hazard determination is also consistent with the "real world" aspects of the problem. As in the case of Euphoria, the government typically learns that a drug poses an imminent hazard through criminal investigations by the DEA or state law enforcement authorities that reveal emerging abuse patterns. See 52 Fed. Reg. 30,174 (1987); App., *infra*, 7a, 9a, 12a. Thus, the Attorney General, who supervises the DEA and coordinates law enforcement activities with the States, is best situated to respond promptly to the imminent public safety menace posed by drugs such as Euphoria, which are produced and sold through clandestine operations.

3. Petitioners argue, nevertheless, that the Attorney General's regulatory and prosecutive functions must be

separated to prevent "'tyrannical' abuse." Br. 15-19. They suggest that the Attorney General might use his Section 201(h) authority to provide a means for prosecuting "targeted" individuals. Br. 18-19. That argument, however, does not rest on the constitutional concept of separation of powers, but rather on the notion that particular officials with the Executive Branch cannot be trusted to execute faithfully Congress's directives. See Pet. Br. 18.

As petitioners recognize (Br. 17 n.12), the Constitution, through the Due Process Clause and the specific guarantees in the Fifth and Sixth Amendments, provides significant safeguards against abuses of the power of prosecution. In addition, Congress can provide further safeguards through statutes and rules of procedure. There is no need for the Court to create additional checks that have no source in the Constitution's text, based on speculative assumptions that public officials will misuse lawful authority. To the contrary, as this Court has explained, Executive Branch officials are entitled to the presumption that "they will act properly and according to law." *FCC* v. *Schreiber*, 381 U.S. 279, 296 (1965). See, *e.g.*, *Fahey* v. *Mallonee*, 332 U.S. 245, 256 (1947).

Moreover, there is little realistic possibility of abuse of the sort that petitioners posit in this case. Petitioners' hypothetical scenario of abuse rests on the assumption that a single individual exercises the rulemaking and prosecutive functions. In reality, those functions are carried out by separate officials: the Administrator of the DEA exercises the authority to schedule substances under Section 201(h) (see p. 39, *infra*), while the individual United States Attorneys both possess and typically exercise the statutory authority to initiate prosecutions. See 28 U.S.C. 547. Thus, there is in practice a separation of the rulemaking and prosecutive functions within the Department of Justice respecting controlled substances. The potential abuse that petitioners posit is no more likely to occur in this case than in any case where

the violation of an administrative regulation may provide the basis for a criminal prosecution.[23]

In any event, petitioners fail to identify any such abuse in this case. They concede that Euphoria meets the legislative standards for designation as a schedule I controlled substance, and they do not contend that the listing of Euphoria was designed to "target[]" them for prosecution. Indeed, the fact that the government lists a controlled substance through a prospective rule of general application all but eliminates any possibility of petitioners' hypothesized abuse. Moreover, as we explain in greater detail below, the government's actions are subject to judicial review at the conclusion of the permanent listing and in the course of an enforcement proceeding. That review is a sufficient safeguard "against statutory or constitutional excesses." *American Power & Light Co.* v. *SEC*, 329 U.S. 90, 106 (1946).[24]

4. Petitioners contend that Congress's action in this case is "entirely unprecedented in our history" and that "[n]o case supports" upholding the authority of the Attorney General both to regulate legislatively identified activity and to prosecute violation of those regulations as a crime. Br. 19, 20. Those assertions are not accurate.

[23] While the Attorney General supervises both the U.S. Attorneys and the DEA Administrator, it likewise can be said that the President supervises every agency that promulgates criminally enforceable regulations and also supervises the criminal enforcement of those regulations. Thus, the potential for abuse that petitioners posit theoretically exists in every case where a regulation may serve as the predicate for a criminal offense.

[24] Petitioners concede (Br. 15), that Congress can combine regulatory and civil enforcement functions in a single agency. See, *e.g.*, *American Power & Light Co.* v. *SEC*, 329 U.S. at 104-106; *National Broadcasting Co.* v. *United States*, 319 U.S. at 225-226. The principle that sustains that result is equally applicable here: the executive official acts pursuant to legislative direction, and his exercise of discretion is subject to judicial oversight at the conclusion of the rulemaking (see *National Broadcasting Co.*, 319 U.S. at 193) or in subsequent enforcement proceedings (see *American Power & Light Co.*, 329 U.S. at 96, 105-106).

Congress has granted and the courts have uniformly upheld the Attorney General's authority to list drugs permanently as controlled substances.[25] In addition, Congress long has authorized the Attorney General to identify prohibited prison contraband and prosecute persons who introduce it into prison. 18 U.S.C. 1791, 4001. Prior to 1984, Section 1791 provided that:

> Whoever, contrary to any rule or regulation promulgated by the Attorney General, introduces or attempts to introduce into or upon the grounds of any Federal penal or correctional institution or takes or attempts to take or send therefrom any thing whatsoever, shall be imprisoned not more than ten years.

18 U.S.C. 1791 (1982). The courts uniformly upheld the constitutionality of that statute, which in petitioners' terminology combined "crime-defining and crime-prosecuting authority" (Br. 19). See S. Rep. No. 225, *supra*, at 380 n.1.[26] Congress amended that statute in 1984 to ensure that the statute would reach possession as well as introduction of contraband. See *id.* at 380. Congress's delegation to the Attorney General under the past and

[25] See, *e.g.*, *United States* v. *Alexander*, 673 F.2d 287 (9th Cir.), cert. denied, 459 U.S. 876 (1982); *United States* v. *Barron*, 594 F.2d 1345 (10th Cir.), cert. denied, 441 U.S. 951 (1979); *United States* v. *Gordon*, 580 F.2d 827 (5th Cir.), cert. denied, 439 U.S. 1051 (1978); *United States* v. *Roya*, 574 F.2d 386 (7th Cir.), cert. denied, 439 U.S. 857 (1978); *United States* v. *Pastor*, 557 F.2d 930 (2d Cir. 1977). The statutory criteria governing a Section 201(h) temporary scheduling are as specific as—and the penalties for violations are no more stringent than—those governing permanent scheduling.

[26] See, *e.g.*, *United States* v. *Koopmans*, 757 F.2d 901 (7th Cir. 1985); *United States* v. *Chatman*, 538 F.2d 567 (4th Cir. 1976); *United States* v. *Park*, 521 F.2d 1381 (9th Cir. 1975); *United States* v. *Berrigan*, 482 F.2d 171 (3d Cir. 1973); *Carter* v. *United States*, 333 F.2d 354 (10th Cir. 1964).

present versions of 18 U.S.C. 1791 is at least as broad as that under Section 201(h).[27]

C. Congress Has Provided Constitutionally Adequate Judicial Oversight Of Section 201(h) Scheduling Decisions

Petitioners also contend that Section 201(h) is an unlawful delegation because Congress has failed to set out adequate provisions for judicial review of temporary scheduling decisions. Petitioners' argument, however, rests in large part on a misunderstanding of Section 201(h).

1. As petitioners recognize, the Controlled Substances Act provides for judicial review of permanent scheduling decisions following the issuance of a final rule. CSA § 507, 21 U.S.C. 877.[28] Thus, the Attorney General's decision to list a substance on schedule I is subject to judicial review under Section 507 if the substance is permanently listed—a process that must be completed within 18 months of the temporary listing. See CSA § 201(h)(2).

Petitioners object that Congress, through Section 201(h)(6), has precluded Section 507 judicial review during the period of up to 18 months that the temporary

[27] As another example, Congress has granted the Attorney General rulemaking authority respecting aliens and nationality, 8 U.S.C. 1103(a), and violation of such regulations may be the predicate for criminal enforcement, see 8 U.S.C. 1324(a).

[28] Section 507 of the Controlled Substances Act specifically states that "any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located." 21 U.S.C. 877. That provision grants a person the right to seek review of a final determination to list a substance permanently on one of the controlled substances schedules. See, *e.g.*, *Grinspoon* v. *DEA*, 828 F.2d 881 (1st Cir. 1987); *Reckitt & Colman, Ltd.* v. *DEA*, 788 F.2d 22 (D.C. Cir. 1986).

listing is in effect. See 21 U.S.C. 811(h)(6). Section 201(h)(6), however, is simply designed to postpone suits challenging the listing decision until the administrative process has run its course. A temporary listing of a substance under Section 201(h) is the first step in the process of determining whether the substance should be permanently listed on a controlled substances schedule. The Attorney General's basis for listing the substance temporarily is open to public comment and reconsideration in the course of the Section 201(a) rulemaking for permanent listing. During that rulemaking, the Attorney General may decide that the substance should be listed on a different schedule or not listed at all. Hence, judicial review of the temporary listing decision prior to completion of the rulemaking would be premature and might prove entirely unnecessary.[29]

2. Petitioners nevertheless contend that Section 201(h) is an unconstitutional delegation of authority because Section 201(h)(6) denies them an opportunity, pending the permanent listing decision, to have a court

[29] Cf. *McGee* v. *United States*, 402 U.S. 479, 483 (1971) (noting that recourse to the administrative process may cure or render moot the defects later complained of in court). The House Committee on the Judiciary explained that the limitation on judicial review in Section 201(h)(6) "conforms to the general practice for temporary, emergency orders such as this procedure." H.R. Rep. No. 835, *supra*, at 13. For example, the Toxic Substances Control Act provides that a rule respecting toxic substances may be made immediately effective for the interim period between its proposal in the *Federal Register* and final action on the proposal if activities respecting the substance are "likely to result in an unreasonable risk of serious or widespread injury to health or the environment" and immediate effectiveness of the rule "is necessary to protect the public interest." 15 U.S.C. 2605(d)(2)(A). Such emergency rules "shall not, for purposes of judicial review, be considered final agency action." *Ibid.* Similarly, the FDA may issue an immediate ban on a dangerous medical device if the device "presents an unreasonable, direct, and substantial danger to the health of individuals," 21 U.S.C. 360f(b), and such a temporary regulation is not subject to judicial review until it has been finalized after completed rulemaking proceedings, 21 U.S.C. 360g(a)(5).

"'ascertain whether the will of Congress has been obeyed.'" Br. 24, quoting *Skinner*, 490 U.S. at 218. It is far from clear that this challenge, even if sustained, would warrant reversal of their convictions.[30] In any event, however, Section 201(h)(6) does not foreclose judicial oversight of the Attorney General's action during that period. As the court of appeals properly recognized, an individual who is prosecuted for a drug violation based on a temporarily listed substance may challenge the legality of the temporary listing as a defense to the prosecution. J.A. 33 n.2, 42-43.

Under the principle of sovereign immunity, an individual has no general right to bring a lawsuit against the government challenging sovereign action. See, *e.g.*, *Larson* v. *Domestic & Foreign Commerce Corp.*, 337 U.S. 682 (1949).[31] Nevertheless, Congress frequently authorizes individuals to bring suits against the government (or its officers)—as in Section 507 of the Controlled Substances Act—to review such action at an appropriate time. See also, *e.g.*, Administrative Procedure Act, 5 U.S.C. 701 *et seq.* (permitting review of final agency action). The presence or absence of a provision creating a right to seek judicial review of agency action, however, generally does not prevent an individual from

[30] Petitioners did not seek review of the Attorney General's scheduling decision either during or after completion of the permanent rulemaking, nor do they argue that Euphoria was improperly listed as a Schedule I substance. See J.A. 33. Thus, Section 201(h)(6)'s preclusion of judicial review did not affect them in any way. For that reason it is questionable whether petitioners have standing to challenge the constitutionality of that provision. Even if they have standing, petitioners would be entitled to reversal of their convictions based on their challenge to the effect of Section 201(h)(6) only if that paragraph were deemed non-severable from the remainder of the subsection. See 28 U.S.C. 2111.

[31] See generally Cramton, *Nonstatutory Review of Federal Administrative Action: The Need For Statutory Reform of Sovereign Immunity, Subject Matter Jurisdiction, And Parties Defendant*, 68 Mich. L. Rev. 387 (1970) (describing the evolution of sovereign immunity and its exceptions).

challenging agency regulations or administrative determinations as a defense to a criminal action brought to enforce them.[32]

While Section 201(h)(6) postpones an individual's right to seek judicial review of a listing decision under Section 507, it does not affect the individual's right to challenge the listing as a defense to a criminal enforcement action brought during the period that the drug was temporarily listed as a schedule I substance. As petitioners acknowledge (Br. 27), there is a strong presumption favoring judicial oversight of agency action.[33] When Congress wishes to prevent judicial inquiry into agency action in an enforcement proceeding, it typically makes that wish explicit.[34] There is no clear indication in the

[32] See, *e.g.*, *Boyce Motor Lines, Inc.* v. *United States*, 342 U.S. 337 (1952) (criminal enforcement of an ICC regulation); *Estep* v. *United States*, 327 U.S. 114 (1946) (criminal enforcement of Selective Service designation); *Monongahela Bridge Co.* v. *United States*, *supra* (criminal enforcement of the Secretary of War's determination that a bridge obstructed navigation); *Union Bridge Co.* v. *United States*, *supra* (same). The APA also incorporates that general rule, providing that "[e]xcept to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement," 5 U.S.C. 703. That provision simply "restates existing law." U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* 99 (1947). See also *Administrative Procedure in Government Agencies*, S. Doc. No. 8, 77th Cong., 1st Sess. 115 (1941).

[33] See *McNary* v. *Haitian Refugee Center, Inc.*, No. 89-1332, slip. op. 16 (Feb. 20, 1991) (it "is presumable that Congress legislates with knowledge of * * * our well-settled presumption favoring interpretations of statutes that allow judicial review of administrative action"). See also, *e.g.*, *Bowen* v. *Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986); *Califano* v. *Sanders*, 430 U.S. 99, 109 (1977); *Dunlop* v. *Bachowski*, 421 U.S. 560, 567 (1975); *Johnson* v. *Robison*, 415 U.S. 361, 373-374 (1974).

[34] See, *e.g.*, Clean Air Act, § 307(b)(2), 42 U.S.C. 7607(b)(2) (providing that EPA action that is reviewable under Section 307(b)(1) "shall not be subject to judicial review in civil or criminal proceedings for enforcement").

Controlled Substances Act or its legislative history that Congress intended to withdraw that right here. Rather, it is clear from the structure of the statute that Section 201(h)(6)'s limitation on "judicial review," 21 U.S.C. 811(h)(6), pertains only to the remedy that Congress provided in Section 507, allowing aggrieved parties to seek "judicial review." 21 U.S.C. 877. No court has held, as petitioners would have it, that Section 201(h)(6) precludes an individual from challenging a temporary scheduling decision as a defense to a prosecution. Petitioners' argument accordingly is without merit.[35]

3. Petitioners contend (Br. 28-30) that even if judicial review of a Section 201(h) scheduling order is available in an enforcement proceeding, the statutory scheme is unconstitutional because it does not provide for a pre-enforcement challenge to the validity of the administrative determination. It is well settled, however, that the Constitution does not require "that there be judicial inquiry before discretion can be exercised." *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 598-599

[35] In other contexts, this Court has been unwilling to deny judicial inquiry into the legality of an administrative regulation in a criminal enforcement proceeding where Congress has not unambiguously precluded such inquiry. For example, in *Estep* v. *United States*, 327 U.S. 114 (1946), this Court held that a draftee who faced criminal prosecution for refusing to submit to military induction could raise the defense that the draft board's actions were lawless and outside its jurisdiction, despite a statutory provision rendering the decisions of the local draft boards "final" except for available administrative review. The Court stated that courts presumptively have the power to review administrative action when exercising "the general jurisdiction which Congress has conferred upon them." *Id.* at 119-120. Although noting that "except when the Constitution requires it, judicial review of administrative action may be granted or withheld as Congress chooses," *ibid.*, the Court stated that it would not "readily infer that Congress departed so far from the traditional concepts of a fair trial when it made the actions of the local boards 'final' as to provide that a citizen of this country should go to jail for not obeying an unlawful order of an administrative agency," *id.* at 122. See also *Adamo Wrecking Co.* v. *United States*, 434 U.S. 275, 285 (1978) (interpreting Clean Air Act § 307(b)(2)).

(1950).[36] Congress can and frequently does deny pre-enforcement review of regulatory actions.[37]

Petitioners cite no case holding that pre-enforcement review of administrative determinations is constitutionally required. As petitioners recognize (Br. 33), this Court has upheld Congress's power to restrict pre-enforcement review, even where important liberty interests are at stake. For example, in *Clark* v. *Gabriel*, 393 U.S. 256 (1968), this Court held that pre-enforcement review of a military induction determination was not constitutionally required even though the induction determination would directly affect an individual's liberty and disobedience would result in criminal prosecution. The Court observed that pre-induction review would result in "litigious interruptions" of induction procedures and concluded:

> We find no constitutional objection to Congress' thus requiring that assertion of a conscientious objector's claims such as those advanced by appellee be deferred until after induction, if that is the course he chooses, whereupon habeas corpus would be an

[36] In *Ewing*, the Court rejected a manufacturer's claim that he was entitled under the Due Process Clause to pre-enforcement review of a determination that vitamin products were misbranded and subject to seizure, observing that "it has never been held that the hand of government must be stayed until the courts have an opportunity to determine whether the government is justified in instituting suit in the courts." 339 U.S. at 599. The Court observed that if the administrative determination were subject to pre-enforcement review, the "means which Congress provided to protect consumers against the injurious consequences of protracted proceedings would then be seriously impaired." *Id.* at 601.

[37] See, *e.g.*, *Witmer* v. *United States*, 348 U.S. 375, 377 (1955) (noting that there "is no direct judicial review" of a military induction determination). See also, *e.g.*, APA, 5 U.S.C. 701(a)(1) (recognizing that statutes may preclude judicial review entirely); Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, 42 U.S.C. 9613(h) (precluding pre-enforcement review of government hazardous substance clean-up remedies); note 29, *supra*.

> available remedy, or until defense of the criminal prosecution which would follow should he press his objections to his classification to the point of refusing to submit to induction.

393 U.S. at 258-259.

Petitioners attempt to distinguish *Clark* on the grounds that (1) that case involved "military necessity"; (2) the agencies involved were required to make a large number of individual determinations; and (3) habeas corpus relief was available. Br. 33. None of those distinctions is persuasive. First, the government's interest in protecting the public from the imminent danger of hazardous drugs, such as Euphoria, poses a "necessity" different in kind but no less pressing in degree than military conscription. See *Ewing*, 339 U.S. at 599-600. Second, Congress's judgment that pre-enforcement review would thwart the regulatory process is equally valid here, where there is a need for immediate regulation of dangerous substances pending permanent rulemaking. *Id.* at 601. Third, there is no need for habeas corpus relief in the present case because the Attorney General's regulatory action—which prohibits the sale of an imminently hazardous substance for a maximum of 18 months, pending completion of formal rulemaking—does not directly result in a deprivation of liberty.

Petitioners fail to identify any substantial liberty interest that would be served by pre-enforcement review. Petitioners principally contend that pre-enforcement review is necessary to save individuals from the "fear and anxiety" (Br. 28-30) of a criminal prosecution. As petitioners acknowledge (Br. 34), however, pre-enforcement review would do little to allay the apprehension of criminal prosecution, because the provision of review, by itself, would not stay the effectiveness of a scheduling order. Rather, individuals in petitioners' business can avoid that "fear and anxiety" of criminal prosecution by curtailing their distribution of substances that the

government has determined to be hazardous during the period of temporary regulation, presenting their challenges to the government's determination in the rulemaking proceedings, and then (if necessary) seeking judicial review of the permanent listing. Thus, the individuals affected by the Attorney General's temporary scheduling decisions have an adequate judicial remedy—one that was not available to the defendants in *Clark*—for obtaining review of the administrative decision.[38]

II. THE ATTORNEY GENERAL LAWFULLY SUBDELEGATED HIS SECTION 201(h) AUTHORITY TO THE ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION

Petitioners also contend (Br. 35-38) that their convictions should be reversed because the Attorney General unlawfully delegated his authority to schedule controlled substances under Section 201(h) to the Administrator of the DEA. See 28 C.F.R. 0.100(b).[39] Petitioners do not argue that there is any constitutional impediment to that subdelegation, nor do they argue that

---

[38] As the record in this case indicates, parties who distribute drugs illicitly are not likely in any event to avail themselves of pre-enforcement judicial review. Petitioners have not questioned the merits of the government's decision to schedule Euphoria. They did not submit comments in the Section 201(a) or the Section 201(h) rulemakings respecting the drug, and they have never pretended to be legitimate drug manufacturers or distributors.

[39] The Attorney General's subdelegation regulation provides that "[t]he following-described matters are assigned to, and shall be conducted, handled, or supervised by, the Administrator of the Drug Enforcement Administration":

> (b) Functions vested in the Attorney General by the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. This will include functions which may be vested in the Attorney General in subsequent amendments to the Comprehensive Drug Abuse Prevention and Control Act of 1970, and not otherwise specifically assigned or reserved by him.

28 C.F.R. 0.100(b).

the delegation regulation itself is deficient in any respect. Petitioners contend only that Congress has not empowered the Attorney General to subdelegate his authority under Section 201(h). In fact, Congress has clearly authorized that subdelegation of authority.

1. Two relevant statutory provisions authorize the Attorney General to delegate his powers under Section 201(h) to the Administrator. First, Section 4(c) of the Act of September 6, 1966, which reorganized the Department of Justice, provides that the Attorney General "may from time to time make such provisions as he considers appropriate authorizing the performance by any other officer, employee, or agency of the Department of Justice of any function of the Attorney General." 28 U.S.C. 510. Second, Section 501(a) of the Controlled Substances Act provides that the Attorney General "may delegate any of his functions under this subchapter to any officer or employee of the Department of Justice." 21 U.S.C. 871(a).[40] The Attorney General's delegation of authority to the Administrator contained in 28 C.F.R. 0.100(b) rests squarely on those statutory provisions. See 52 Fed. Reg. 24,447 (1987).

Petitioners speculate (Br. 35-38) that Congress intended that the Attorney General's temporary listing authority would be nondelegable. The clear, broad, and unqualified terms of both Section 4(c) and Section 510, however, unambiguously encompass the temporary listing authority set forth in Section 201(h). Additionally, Section 201(h) does not impose any limitations on the Attorney General's power to subdelegate the authority contained therein. Thus, the text of the relevant statutory provisions provides no basis for the exception petitioners suggest.

2. Petitioners' suggestion that the Court create an exception for Section 201(h) is also inconsistent with this Court's decisions interpreting other statutory delegation provisions. For example, in *Fleming* v. *Mohawk Wrecking & Lumber Co.*, 331 U.S. 111 (1947), this Court upheld the authority of the Administrator of the Emergency Price Control Act to delegate to district directors his authority to issue subpoenas. That delegation rested on a general provision of the statute stating that the Administrator could appoint employees to carry out his functions and duties under the statute and that any duly authorized representative of the Administrator may exercise any and all of his powers. See *id.* at 120-122. The Court found no indication in the statute or in its legislative history that Congress intended to single out the subpoena authority as nondelegable. *Ibid.*[41]

Petitioners rely on *United States* v. *Giordano*, 416 U.S. 505 (1974), for a different result. That case, however, supports our position. In *Giordano*, Congress found from the language of the statute at issue, Title III of the Omnibus Crime Control and Safe Streets Act of 1968, 18 U.S.C. 2510 *et seq.*, that Congress intended to preclude the Attorney General from relying on his general delegation authority under Section 4(c) to subdelegate his authority to apply for a wiretap order. Section 802 of Title III, 18 U.S.C. 2516 (1970), did not grant the Attorney General unfettered authority to apply for a wiretap order, but specifically stated that the authority rested in the "Attorney General, or any Assistant At-

[40] That subchapter includes Sections 101 through 709 of the Controlled Substances Act, 21 U.S.C. 801-904.

[41] The Court distinguished a previous decision, *Cudahy Packing Co.* v. *Holland*, 315 U.S. 357 (1942), holding that the subpoena authority under the Fair Labor Standards Act of 1938, ch. 676, § 4(b), 52 Stat. 1061-1062, did not authorize the Administrator to delegate his power under that Act to sign and issue subpoenas. The Court observed that the legislative history of the Act revealed that a provision authorizing subdelegation of the subpoena authority had been eliminated from the bill in the conference committee. *Fleming*, 331 U.S. at 120. Moreover, the statute considered in *Cudahy* specifically identified the powers to gather data and to make investigations as delegable, and therefore by implication indicated that powers not specified were intended to be nondelegable. 331 U.S. at 121.

torney General specially designated by the Attorney General."

The Court accepted the proposition that the Attorney General's general delegation authority under Section 4(c) would permit the delegation of all functions previously or thereafter vested in the Attorney General unless a specific provision restricted that delegation authority. 416 U.S. at 512-514. The Court concluded, however, that Congress clearly expressed its intention to supersede the Attorney General's general delegation authority by specifically identifying in Section 802 who—in addition to the Attorney General—could authorize a wiretap application. The Court found that "[t]his interpretation of the statute is also strongly supported by its purpose and legislative history." *Ibid.*[42]

Petitioners do not point to anything in the Controlled Substances Act (or its legislative history) indicating that Congress intended to prohibit the Attorney General from subdelegating his temporary scheduling authority. Petitioners simply argue that the authority to list schedule I substances temporarily "is both so vast and so unbridled that congressional authority to subdelegate should be very clear before subdelegation is permitted." Br. 36. As we have discussed, above, the Section 201(h) scheduling authority is neither vast nor unbridled. In any event, both *Giordano* and *Fleming* indicate that Congress need not expressly authorize subdelegation when a general subdelegation provision exists. See *Giordano*, 416 U.S. at 513-514; *Fleming*, 331 U.S. at 121. Rather, a restriction on subdelegation must appear in the statute

[42] A previous version of the relevant provision that allowed delegation to an officer of the Department of Justice was changed to the enacted version in response to the specific concern that the authority to authorize wiretap applications should be limited. 416 U.S. at 516-517. The legislative history in other respects reflected Congress's understanding that the authority to authorize wiretap applications was to be limited to the persons identified in Section 802. See 416 U.S. at 518-522.

granting new authority.[43] There is no such restriction—and no basis for inferring one—in this instance. Accordingly, the Attorney General lawfully delegated his temporary listing authority (together with the permanent listing authority) to the Administrator.

[43] On other occasions, when Congress has sought to restrict the Attorney General's authority to subdelegate his powers, Congress has specifically limited the subdelegation authority. See, *e.g.*, 18 U.S.C. 245(a)(1) (certain prosecutions under the Civil Rights Act of 1968 are authorized only on the certification of "the Attorney General, the Deputy Attorney General, the Associate Attorney General, or any Assistant Attorney General specially designated by the Attorney General * * * which function of certification may not be delegated"); 18 U.S.C. 1073 (prosecutions for flight to avoid prosecution or to avoid giving testimony may be initiated "only upon formal approval in writing by the Attorney General, the Deputy Attorney General, the Associate Attorney General or an Assistant Attorney General of the United States, which function of approving prosecutions may not be delegated"); 18 U.S.C. App. at 711 (§ 14) (functions of the Attorney General under the Classified Information Procedures Act "may be exercised by the Deputy Attorney General, the Associate Attorney General, or by an Assistant Attorney General designated by the Attorney General for such purpose and may not be delegated to any other official"). With respect to other government agencies, Congress likewise has frequently, and explicitly, identified the authorities for which delegation is restricted. See, *e.g.*, 5 U.S.C. 3312(b), 3318(b)(4), 3504(b); 10 U.S.C. 809(c), 1370(a)(2), 1587(d), 1622(d), 1623(c), 2304(d)(2), 2356(a), 2435(c)(2); 12 U.S.C. 3502(c); 31 U.S.C. 1344(d)(3), 3553(e); 38 U.S.C. 5025(b)(3)(C); 40 U.S.C. 759(d)(1); 41 U.S.C. 10b-1(e), 253(d)(2), 421(d), 423(d)(7)(B); 42 U.S.C. 8374(e), 8511(f), 8513(g), 8521(c)(4); 49 U.S.C. 322(b).

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

KENNETH W. STARR
Solicitor General

ROBERT S. MUELLER, III
Assistant Attorney General

WILLIAM C. BRYSON
Deputy Solicitor General

JEFFREY P. MINEAR
Assistant to the Solicitor General

RICHARD A. FRIEDMAN
Attorney

MARCH 1991

APPENDIX A

FOOD AND DRUGS—DRUG ABUSE PREVENTION TEMPORARY SCHEDULING TO AVOID IMMINENT HAZARDS TO PUBLIC SAFETY
§ 201(h), 21 U.S.C. 811(h)

(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) of this section relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not listed in any other schedule in section 812 of this title or if no exemption or approval is in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355]. Such an order may not be issued before the expiration of thirty days from—

(A) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and

(B) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) The scheduling of a substance under this subsection shall expire at the end of one year from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) of this section with respect to the substance, extend the temporary scheduling for up to six months.

(3) When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to

the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c) of this section, including actual abuse, diversion from legitimate channels. and clandestine importation, manufacture, or distribution.

(4) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) of this section with respect to such substance.

(6) An order issued under paragraph (1) is not subject to judicial review.

DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION: GENERAL FUNCTIONS
28 C.F.R. 0.100

The following-described matters are assigned to, and shall be conducted, handled, or supervised by, the Administrator of the Drug Enforcement Administration:

(a) Functions vested in the Attorney General by sections 1 and 2 of Reorganization Plan No. 1 of 1968.

(b) Functions vested in the Attorney General by the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. This will include functions which may be vested in the Attorney General in subsequent amendments to the Comprehensive Drug Abuse Prevention and Control Act of 1970, and not otherwise specifically assigned or reserved by him.

(c) Functions vested in the Attorney General by section 1 of Reorganization Plan No. 2 of 1973 and not otherwise specifically assigned.

APPENDIX B

Scheduling Recommendation for 4-methylaminorex

Prepared by

Drug Control Section
Office of Diversion Control
Drug Enforcement Administration

September 1988

Introduction

The Drug Enforcement Administration (DEA) has gathered information relevant to the abuse potential, trafficking and actual abuse of 4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine (4-methylaminorex). 4-Methylaminorex is an analog of aminorex, an anorectic agent previously marketed in Europe. 4-Methylaminorex has appeared in the illicit drug traffic and pursuant to the emergency scheduling provision of the Controlled Substances Act (CSA) (21 U.S.C. 811(h)), was controlled by temporary placement into Schedule I, effective October 15, 1987 (52 FR 38225). The temporary scheduling of 4-methylaminorex expires one year from the effective date of control unless traditional scheduling procedures have been initiated in accordance with 21 U.S.C. 811(a).

Clandestine synthesis of 4-methylaminorex was first detected following seizure by Florida law enforcement officials of samples purported to be "speed." At least two deaths have been reported as a consequence of 4-methylaminorex abuse. Continued control of 4-methylaminorex is critical to law enforcement initiatives aimed at eliminating the manufacture and distribution of a potent amphetamine-like substance.

Criteria for inclusion of a substance in Schedule I

The necessary criteria for placing a substance in Schedule I, as set forth in 21 U.S.C. 812(b)(1) of the CSA, are as follows:

(1) *the drug or other substance has a high potential for abuse;*

(2) *the drug or other substance has no currently accepted medical use in treatment in the United States; and*

(3) *there is a lack of accepted safety for use of the drug or other substance under medical supervision.*

Potential for abuse

The term "potential for abuse" is described in House Report No. 91-1444 to include any or all of four elements. These elements and their applicability in determining the abuse potential of 4-methylaminorex as follows:

(A) *Evidence that individuals are taking the drug in amounts that create a hazard to their health or the safety of the community.*

One individual from Florida and another from Tennessee have died as a result of 4-methylaminorex abuse. Another individual using 4-methylaminorex was apprehended while running down the middle of a highway in Florida.

(B) *Diversion from legitimate channels.*

There is no known legitimate commercial manufacturer of 4-methylaminorex.

(C) *Self-administration of the drug without medical supervision.*

DEA laboratories have analyzed a number of exhibits and identified them as 4-methylaminorex. These exhibits, when summed, weighed over 1000 grams. A reasonable estimate of dosage unit weight for 4-methylaminorex is 20 mg. Therefore, seizures to date have amounted to over 50,000 dosage units.

(D) *Evidence that the drug in question is so related in its action to another drug or drugs that it is likely that it will have the same potential for abuse.*

The pharmacological profile of 4-methylaminorex closely resembles that of amphetamine. In McNeil

Laboratories Department of Pharmacology Report No. 49, 4-methylaminorex is described as "a potent central nervous system stimulant. The spectrum of pharmacological actions produced by McN-822 is similar in several respects to that produced by amphetamine." The report goes on to describe a number of autonomic and behavioral effects of 4-methylaminorex that support their conclusions regarding its stimulant effects. In particular it was noted that 4-methylaminorex (5mg/kg. i.v. in dog) produced substantial increases in mean blood pressure by way of sympathomimetic actions. Behavioral actions were also studied in dogs. Following doses of 1-2 mg-kg, 4-methylaminorex administration produced signs of restlessness, alertness, and dilated pupils and "a period of increased coordinated motor activity follows during which panting is clearly audible." When the dose was increased to 5 mg/kg, stereotyped behavior (repetitive motor movements) predominated, followed by seizures, loss of consciousness, respiratory depression and death. Amphetamine was reported to produce a similar pattern of behavioral changes in the dog.

In a study of the sympathomimetic actions of 4-methylaminorex, Yelnowsky and Katz [1] reported that cross tolerance of this compound with amphetamine was observed with respect to pressor actions. Furthermore they noted that, like amphetamine, 4-methylaminorex produces its sympathomimetic actions indirectly by way of released catecholamines.

Experimental studies of the anorectic actions of 4-methylaminorex have shown that it potently sup-

[1] Yelnowsky, J. and Katz, R. Sympathomimetic actions of cis-2-amino-4-methyl-5-phenyl-2-oxazoline, J. Pharmacol. Exp. Therap., 141: 180-184, 1963.

presses appetite in rats in a manner similar to amphetamine [2]. Authors Roszkowski and Kelley noted in their summary that "Of the 10 drugs tested 4 were very potent: d-amphetamine, methamphetamine, and two oxazolines, . . . McN-742 . . . and McN-822. . . ." Moreover, " . . . at effective dose levels, all of the anorexigens display a similar degree of central nervous system stimulation."

Review of the Eight Factors listed in 21 U.S.C. 811(c)

(1) Actual or relative potential for abuse.

As stated above, actual abuse has been made evident by the death of at least two individuals abusing 4-methylaminorex. In addition, a number of other individuals have been observed and/or apprehended by officials of the Florida Department of Law Enforcement following abuse of this substance. The serious nature of 4-methylaminorex abuse in Florida has led to the control of this substance within the state's Schedule I category. In a recently published article [4], a clandestine information sheet detailing the effects of 4-methylaminorex was quoted as saying "Potential for Abuse Of course! People have taken considerable overdoses. . . ."

[2] Poos, G.I., Carson, J.R., Rosenau, J.D., Roszkowski, A.P., Kelley, N.M. and McGowin, J., 2-amino-5-Aryl-2-oxazolines. Potent new anorectic agents. J. Med. Chem., 6: 266-272, 1963. Roszkowski, A.P. and Kelley, N.M., A rapid method for assessing drug inhibition of feeding behavior. J. Pharm. Exp. Therap., 140: 367-374, 1963.

[3] D. Inaba and L. Brewer. U4Euh. Microgram, 1987.

(2) Scientific evidence of its pharmacological effects, if known.

See section (D) under Potential for Abuse section.

(3) The state of current knowledge regarding the drug or other substance.

Toxicity

In addition to knowledge concerning the pharmacological actions, a study of toxicity was conducted by investigators at McNeil Pharmaceutical. Based on this data, 4-methylaminorex appears to produce toxic effects associated with the extension of its primary pharmacological action, namely central nervous system stimulation. With increasing dosage, 4-methylaminorex produces an over stimulation of the central nervous system that leads to stereotyped motor activity, seizure activity in the brain and associated convulsions, respiratory failure and death. Commentary from the McNeil Pharmaceutical researchers stresses that "This compound possesses a narrow margin of safety in the dog and should be tested very cautiously in humans."

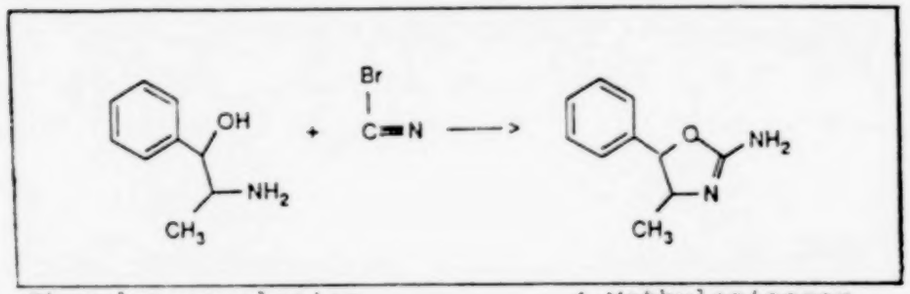
It should be noted that two recent deaths have been attributed to the abuse of 4-methylaminorex[4]. Analyses from the Florida incident indicated the presence of high levels of 4-methylaminorex in the blood (21.3 mg/L) and urine (12.3 mg/L) of the victim.

---

[4] Davis, F.T. and Brewster, M.E., A fatality involving U4Euh, a cyclic derivative of phenylpropanolamine. Case report from the Orlando Crime Laboratory, Orlando, Florida 1987. Personal communication from Ms. G. Armstrong, Naval Investigative Service, Memphis, Tennessee, 1988.

Chemistry

One of the most distressing properties of 4-methylaminorex from a drug control standpoint, is the nature of the chemical procedures involved in its synthesis. By combining phenylpropanolamine and cyanogen bromide in a sodium acetate buffered methanol solution, one obtains high yield synthesis of 4-methylaminorex in a single step (see Figure 1).



Phenylpropanolamine 4-Methylaminorex

Figure 1

In terms of chemical similarity to other psychoactive substances, 4-methylaminorex most closely resembles the anorectic agent, aminorex. Aminorex was marketed in Europe under the trade names **Menocil** and **Apiquel.** Another substance that is chemically similar to 4-methylaminorex is the Schedule IV central nervous system stimulant, pemoline **(Cylert).**

(4) Its history and current pattern of abuse.

Studies on 4-methylaminorex were reported in the scientific literature in the early 1960's and 1970's. Exhibits of clandestinely produced 4-methylaminorex have been obtained since 1986. The pattern of abuse of 4-methylaminorex appears similar to that of am-

phetamine. A clandestine information sheet[5] describes a large dose of 4-methylaminorex as producing "sleeplessness for three days and nights. . . . A few cases of abuse by taking doses for four to six days without sleeping have been reported."

(5) The scope, duration and significance of abuse.

The use of emergency controls on 4-methylaminorex may have played a role in limiting the spread of this substance. Our best estimate of the scope of 4-methylaminorex abuse is that most of the abuse has taken place in Florida, California and probably Pennsylvania with an isolated incident in Tennessee.

(6) What, if any, risk there is to the public health.

4-Methylaminorex produces pharmacological effects that are similar to those of amphetamine and related stimulants. Abuse of this substance should produce the same public health risks as those associated with the abuse of amphetamine, methamphetamine and other potent stimulants. The public health risks attendant to the abuse of stimulants are well established and need not be elaborated here.

(7) Its psychic or physiological dependence liability.

The pharmacological profile of 4-methylaminorex is substantially similar to amphetamine and methamphetamine. Such a profile strongly suggests that abuse of 4-methylaminorex will lead to the typical psychic dependence profile produced by the amphetamines.

---

[5] D. Inaba and L. Brewer. U4Euh. Microgram, 1987.

(8) Whether the substance is an immediate precursor of a substance already controlled under this title.

4-Methylaminorex is not an immediate precursor of any controlled substance.

Summary

Review of the pharmacology of 4-methylaminorex indicates that this substance is a potent amphetamine-like stimulant with a low margin of safety. In the absence of any accepted medical use of the compound, regular control proceedings should be initiated to place 4-methylaminorex into Schedule I of Controlled Substances Act.

Law Enforcement Seizures of 4-Methylaminorex

Date	Location	Type of Action	Amount (grams)
01/06/89	Newark, N.J.	Lab Seizure	102.00
01/06/89	Newark, N.J.	Lab Seizure	0.44
01/06/89	Newark, N.J.	Lab Seizure	0.10
11/16/87	Gainesville, FL	Lab Seizure	14.00
11/16/87	Gainesville, FL	Lab Seizure	0.10
11/16/87	Gainesville, FL	Lab Seizure	28.20
05/01/87	Norristown, PA	Lab Seizure	1000.00
01/29/88	Oakland, CA	Lab Seizure	672.20
08/17/88	Montgomery Cty, IN	U/C Buy	13.00
*** Total ***			1830.04

☆ U. S. GOVERNMENT PRINTING OFFICE: 1991 282061 20440